

REMARKS

Claims 1-46, 48-61, 66, 67, and 72-80 are currently pending. Claims 2-5, 11-45, 47-50, 53-59, 62-65, 68-71, 77-78, and 80 have been cancelled without prejudice. Claims 1, 46, 52, and 72 are currently amended. Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79 are currently pending and under examination.

Support for amendments to Claims 1, 46, and 52 are found throughout the specification and in the claims as originally filed, in particular Claims 4 and 5. Claim 72 is amended to recite "MTAP-binding agent" instead of "MTA-binding agent." The amendments to the claims do not introduce new matter, and Applicants request entry of the amendments to Claims 1, 46, 52 and 72 presented herewith.

Applicants thank the Examiner for allowing Claims 9, 10, 51, 61, 66, 67, 72-76, and 79 in the Office Action mailed November 17, 2005. Applicants thank the Examiner for indicating amendments to overcome objections to Claim 46.

Claim Rejections

Rejections under 35 U.S.C. §112, First Paragraph

With respect to MTAP-binding agents

Claims 1, 6-8, 43, and 52 stand rejected under 35 U.S.C. §112, first paragraph, on grounds that the specification, while being enabling for monoclonal antibody produced by hybridoma cell line ATCC PTA-5001, allegedly does not reasonably provide enablement for other MTAP-binding agents. Applicants point out that Claim 43 has been cancelled without prejudice, thereby obviating the rejection with respect to this claim.

Claims 1, 6-8, and 52, as amended, recite MTAP-binding agents wherein the MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001. It is admitted that the specification is enabling for a monoclonal antibody produced by hybridoma cell line ATCC PTA-5001 (Office Action, page 3, lines 3-4). In light of the enabling disclosure in the specification for the MTAP-binding agents of Claims 1, 6-8, and 52, the rejections under 35 U.S.C. §112, first paragraph should be withdrawn.

With respect to binding to MTAP epitopes

Claims 11-12 and 80 are rejected under 35 U.S.C. §112, first paragraph, on grounds that the specification allegedly does not reasonably provide enablement for "MTAP epitope" as recited in the claims. Applicants point out that Claims 11, 12, and 80 have been cancelled without prejudice, thereby obviating the rejection with respect to these claims.

Rejections under 35 U.S.C. §102(e)

Claims 1-4, 11-12, 52-55, and 57-58 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Carson *et al.* (US2004/0096436). Applicants point out that Claims 2-4, 11-12, 53-55, and 57-58 have been cancelled without prejudice, thereby obviating the rejection with respect to these claims.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1052 (Fed. Cir. 1987), cited at MPEP §2131. Claims 1 and 52, as amended, recite a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001, whereas Carson *et al.* does not disclose a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001. Because Carson *et al.* does not disclose each and every element of Claims 1 and 52, the rejections under 35 U.S.C. §102(e) should be withdrawn.

Rejections under 35 U.S.C. §103

Claims 43-45 are rejected under 35 U.S.C. §103(a) over Carson *et al.* (US2004/0096436) in view of Medenica *et al.* (US 5,744,585). Applicants point out that Claims 43-45 have been cancelled without prejudice, thereby obviating the rejection with respect to these claims.

Claims 1-4, 6-8, 11-12, 52-55, 57-58, and 77-78 are rejected under 35 U.S.C. §103(a) over Carson *et al.* (US2004/0096436) in view of Mulshine *et al.* (US 4,569,788), as allegedly disclosing antibodies that specifically bind MTAP (Carson *et al.*) and the use of antibodies to detect antigens in an embedded biological sample (Mulshine *et al.*). Applicants point out that Claims 2-4, 11-12, 53-55, 57-58, and 77-78 have been cancelled, thereby obviating the rejection with respect to these claims. With respect to Claims 1, 6-8, and 52, Applicants submit that no *prima facie* case of obviousness has been established and therefore, the rejection of Claims 1, 6-8, and 52 should be withdrawn.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See*, MPEP §§ 2142, 2143. If a basic criterion is not met for a claim, then no *prima facie* case of obviousness has been established and the rejection under 35 U.S.C. §103(a) should be withdrawn for that claim.

Cited references do not teach the claimed invention.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974). Claim 1, as amended, recites an MTAP-binding agent that specifically binds to human MTAP protein in an embedded biological sample, wherein the MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001, and the biological sample is not embedded in OCT compound. Claims 6-8, which depend from Claim 1, recite an MTAP-binding agent that specifically binds to a biological sample embedded in paraffin (Claim 6), fixed (Claim 7), or fixed with formalin (Claim 8), wherein the MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001. Claim 52, which depends from Claim 1, recites an MTAP-binding agent that specifically binds to human MTAP protein present in an embedded biological sample and yields a statistical score, based on staining intensities, that permits the identification of an embedded sample comprising cells homozygously deleted for the gene encoding human MTAP protein, wherein said embedded sample is not embedded in OCT compound, and wherein the MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001.

In contrast, the cited references, alone or in combination, do not teach or suggest an MTAP-binding agent that specifically binds to human MTAP protein in an embedded biological sample, wherein the MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001. Because Carson *et al.* and Mulshine *et al.* fail to teach or suggest all the claim limitations of Claims 1, 6-8, or 52, a basic criterion for establishing a *prima facie* case of obviousness has not been met. Because no *prima facie* case of obviousness has been established, the rejection of Claims 1, 6-8, and 52 under 35 U.S.C. §103(a) should be withdrawn.

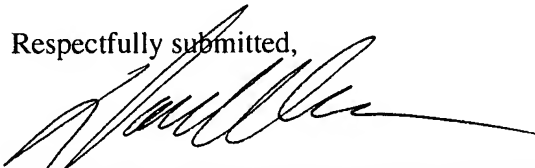
CONCLUSION

Claims 1-46, 48-61, 66, 67, and 72-80 are currently pending. Claims 2-5, 11-45, 47-50, 53-59, 62-65, 68-71, 77-78, and 80 have been cancelled without prejudice. Claims 1, 46, 52, and 72 are currently amended. Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79 are currently pending and under examination.

Applicants submit that Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79 are now in condition for allowance, and request that all outstanding rejections be withdrawn and a notice of allowance be issued for Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79.

Applicants believe that fees are due. Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any overpayments to the above-referenced Deposit Account.

Respectfully submitted,



PILLSBURY WINTHROP SHAW PITTMAN LLP
DONNA O. PERDUE
Reg. No. 51166
Tel. No. 858.509-4093
Fax No. 858.509-4010

Date: May 17, 2006
11682 El Camino Real, Suite 200
San Diego, CA 92130-2092
(619) 234-5000

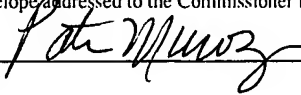
CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

(When using Express Mail, the Express Mail label number is *mandatory*; Express Mail certification is *optional*.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: May 17, 2006

Signature



PATRICIA MUNOZ

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.